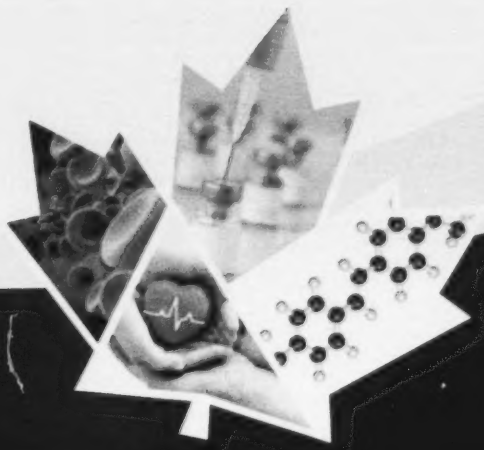
Santé Canada Health Canada

Biologics and Genetic Therapies Directorate

Drug Submission Performance Quarterly Report

April – June

2018



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OVERVIEW

The Biologics and Genetic Therapies Directorate (BGTD) Quarterly Drug Submission Performance Report reflects biologic and radiopharmaceutical drug submission review activity over five consecutive quarters: from April – June 2017 to April – June 2018. Statistics are provided by Submission Type and show the number received the number in workload, the number of decisions and the number of approvals.

General Information

There are several steps involved in the drug submission review[1] and approval process:

- administrative processing,
- regulatory and scientific screening and
- in-depth scientific review.

When deficiencies or non-compliance issues are found, a company may submit responses before a final decision can be reached and thus multiple review cycles may be required. A submission's approval time can vary depending on the number and type of review cycles needed.

Submissions Received are counts of submissions received during the year using the filing date (CR date) which is the date the submission is considered administratively complete by Health Canada.

Workload is the number of submissions "under active review" on the last day of the quarter. **"Backlog"** is the proportion of the workload that is over target. Often the term workload is used to mean the amount of work received over a period of time and is a common source of confusion.

Approvals[2] are Notice of Compliances (NOC) Issued or Issuable. An NOC issuable is when a submission's NOC is placed "on hold" awaiting authorization to market, due to Patented Medicines (NOC) Regulations or due to changes from Prescription to Non-Prescription.

[1] For further clarification refer to the Guidance for Industry: Management of Drug Submissions

[2] Final results from confirmatory trials submitted in the form of an SNDS-C are now included in the SNDS Received, Workload and Performance figures. SNDS-C are not included in the SNDS Approval figures. For further Clarification refer to to the Guidance Document: Notice of Compliance with Conditions (NOC/c).

A **review cycle completion**[3] is counted upon the conclusion of an in-depth scientific review that then results in a decision of approval or non-approval. The time taken is compared to a set performance standard[4] which is based on the type of submission, class and cycle (status). For example, in the case of a Priority NDS, the performance standard is 180 days for Review1 and 90 days for Review2. Health Canada has set a goal of 90% of review cycle completions to be rendered within performance standards.

"First Cycle Review" Approvals are those submissions approved without having to go through several review cycles to resolve submission deficiencies or non-compliance issues, and exclude "refiled"[5] submissions.

Any questions or comments on this report should be forwarded to:

Office of Submissions and Intellectual Property, Biologics and Genetics Therapies Directorate

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Ottawa, Ontario, K1A 0K9

Tel: (613) 941-7281 Fax: (613) 941-0825

Email: hc.osip-bppi.sc@canada.ca

[3] Review cycles include all types e.g. Review 1, Review 2, Review QN. The total number of "review decisions" may surpass the total number of review cycle completions as they include cancellations/withdrawals that occur while the submission is 'inactive'. For example, a withdrawal can be issued when a company fails to respond to a notice of non-compliance within the allotted time frame. A 'Cancelled by Company' is counted as a review decision when a company sends a cancellation letter after the submission's original materials have been accepted for review.

[4] Performance continues to be measured against performance standards for Submission Type/Submission Class/ Status combinations as set out in Appendix 3 of the Guidance for Industry: Management of Drug Submissions .This is not to be confused with the 'UF Review 1 (iteration 1)' performance standards that are employed to measure performance to meet the *User Fees Act* reporting Requirements in the 'Health Canada Departmental Performance Report (DPR).

[5] For further clarification refer to the Guidance for Industry: Management of Drug Submissions

ACRONYMS

Submission Types

CTA	-	Clinical Trial Application
CTA-A	-	Clinical Trial Application-Amendment
DINB	-	Application for a Drug Identification Number - Biological Product
MP-NDS		Pre- New Drug Submission Meeting
MP-SNDS		Pre- Supplemental New Drug Submission Meeting
NDS	-	New Drug Submission
NC	-	Notifiable Change (Level II) – New Drug
PDC	-	Post Din Changes
PRNDS	-	Request for Priority Review Status: New Drug Submission
PRSNDS	-	Request for Priority Review Status: Supplemental New Drug Submission
SNDS	-	Supplemental New Drug Submission
SNDS-C	-	Supplemental New Drug Submission – CONFIRMATORY
YBPR	-	Yearly Biologic Product Report

Documents

NOC	-	Notice of Compliance
NOC-c	-	Notice of Compliance with Conditions
Issuable NOC (Patent)	-	NOC on Hold due to Patented Medicines (NOC) Regulations
Issuable NOC (Rx to OTC)	-	NOC on Hold due to changes (Rx to OTC)
NON	-	Notice of Non-Compliance
NOD	-	Notice of Deficiency
NON Withdrawal	-	Notice of Non-Compliance Withdrawal Letter
NOD Withdrawal	-	Notice of Deficiency Withdrawal Letter

Fee Categories

Fee Category	Fee Category Description
New Active Substance (NAS)	Submission in support of a drug, excluding a disinfectant, that contains a medicinal ingredient not previously approved in a drug for sale in Canada, and that is not a variation of a previously approved medicinal ingredient such as a salt, ester, enantiomer, solvate or polymorph. For biologics, this submission class does not include an NDS in support of a subsequent entry biologic or an SNDS in support of changes to the manufacturing process of biologics.
Clinical or Non-Clinical Data and Chemistry and Manufacturing data	Submissions based on clinical or non-clinical data **and** chemistry and manufacturing data for a drug that does not include a NAS.
Clinical or Non-Clinical Data Only	Submissions based only on clinical or non-clinical data for a drug that does not include a NAS.
Comparative Studies	Submissions based on comparative studies with or without chemistry and manufacturing data for a drug that does not include a NAS. It excludes superiority and non-inferiority studies since they are clinical studies. It also excludes pharmaceutical equivalence studies since they are captured by the chemistry and manufacturing fee.
Chemistry and Manufacturing Data Only	Submissions based only on chemistry and manufacturing data for a drug that does not include a NAS.
Published Data Only	Submissions based only on published clinical or non-clinical data for a drug that does not include a NAS.
Switch from Prescription to Nonprescription Status	Submissions based only on data that support the modification or removal of a medicinal ingredient on the Prescription Drug List. This fee is limited to switches from prescription to nonprescription status when an identical claim is made for an existing drug.
Labelling Only[6]	Submissions of labelling material that do not include supporting clinical or non-clinical data or chemistry and manufacturing data.
Administrative Submission[7]	Submissions in support of a manufacturer or product name change.
Disinfectants[8]	Submissions and applications that include data in support of a disinfectant.
Drug Identification Number (DIN) - Labelling Standards	Applications attesting to compliance with a labelling standard or Category IV Monograph (DINF) for a drug that does not include clinical or non-clinical data or chemistry and manufacturing data.

For further information refer to the Guidance Document - Fees for the Review of Drug Submissions and Applications

[6] For more information, please consult the Guidance Document: Question and Answers about Plain Language Labelling
[7] For additional information, please consult the "Changes in Manufacturer and/or Product Name Policy" (2015)
[8] The non-prescription (or over-the-counter) and disinfectant drug review functions were moved from TPD to the Natural and Non-prescription Health Products Directorate (NNHPD) on July 1, 2013. These products are reported on in a separate NNHPD Drug Submission Performance Report.

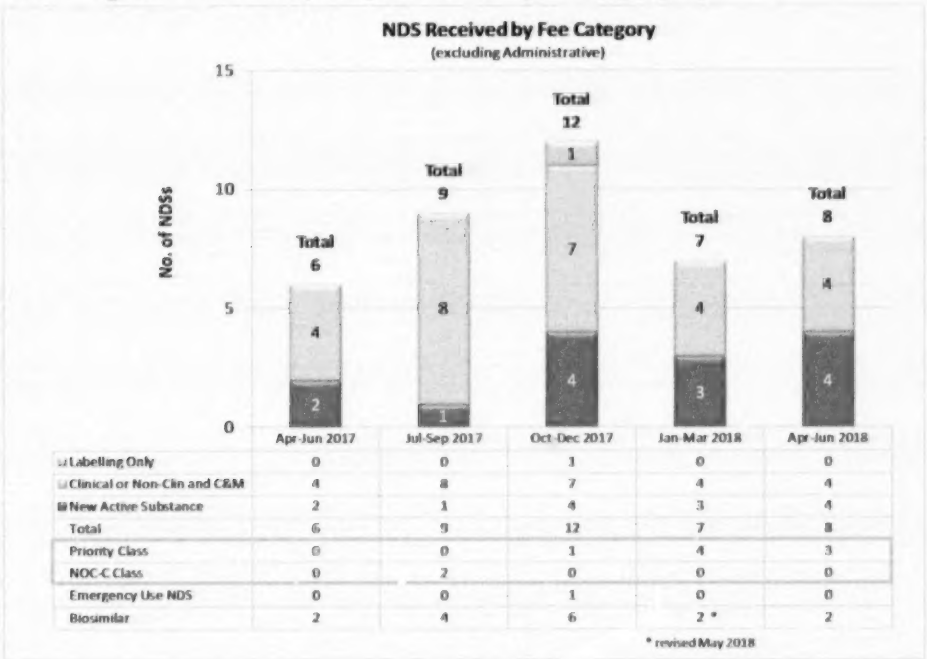
New Drug Submissions (NDS)

&

Supplemental New Drug Submissions (SNDS)

SUBMISSIONS RECEIVED[9], [10]

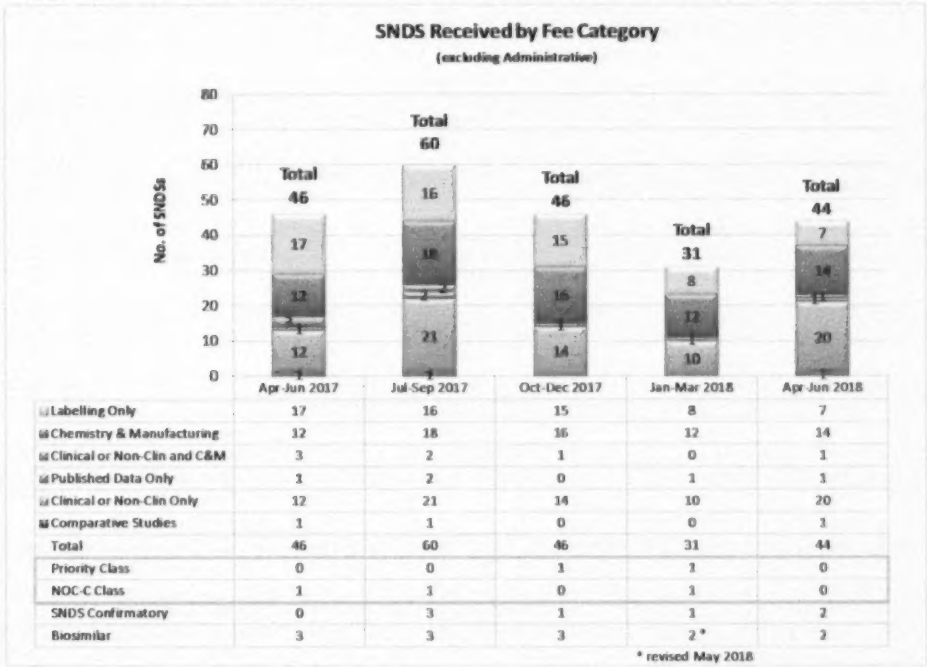
New Drug Submissions (NDS) Received by Fee Category



	Apr-Jun 2017	Jul-Sep 2017	Oct-Dec 2017	Jan-Mar 2018	Apr-Jun 2018
Labelling Only	0	0	1	0	0
Clinical or Non-Clin and C&M	4	8	7	4	4
New Active Substance	2	1	4	3	4
Total	6	9	12	7	8
Priority Class	0	0	1	4	3
NOC-C Class	0	2	0	0	0
Emergency Use NDS	0	0	1	0	0
Biosimilar	2	4	6	2 *	2

* revised May 2018

Supplemental New Drug Submissions (SNDS) Received by Fee Category



	Apr-Jun 2017	Jul-Sep 2017	Oct-Dec 2017	Jan-Mar 2018	Apr-Jun 2018
Labelling Only	17	16	15	8	7
Chemistry & Manufacturing	12	18	16	12	14
Clinical or Non-Clin and C&M	3	2	1	0	1
Published Data Only	1	2	0	1	1
Clinical or Non-Clin Only	12	21	14	10	20
Comparative Studies	1	1	0	0	1
Total	46	60	46	31	44
Priority Class	0	0	1	1	0
NOC-C Class	1	1	0	1	0
SNDS Confirmatory	0	3	1	1	2
Biosimilar	3	3	3	2 *	2

* revised May 2018

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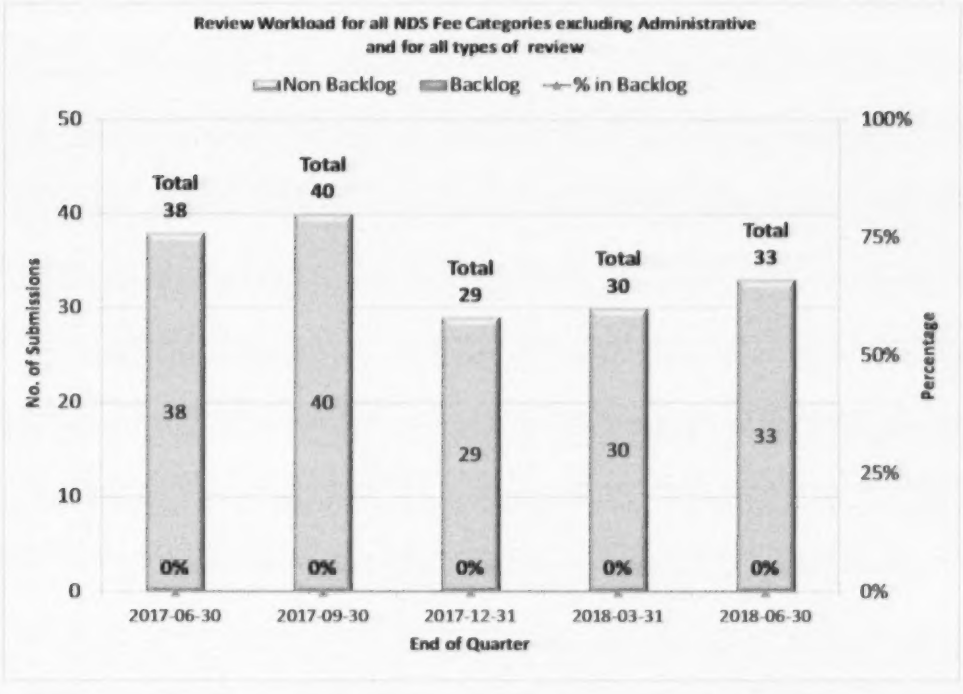
[9] **Biosimilar**: A biologic drug that enters the market subsequent to a version previously authorized in Canada, and with demonstrated similarity to a reference biologic drug. Biosimilar relies in part on prior information regarding safety and efficacy that is deemed relevant due to the demonstration of similarity to the reference biologic drug and which influences the amount and type of original data required.

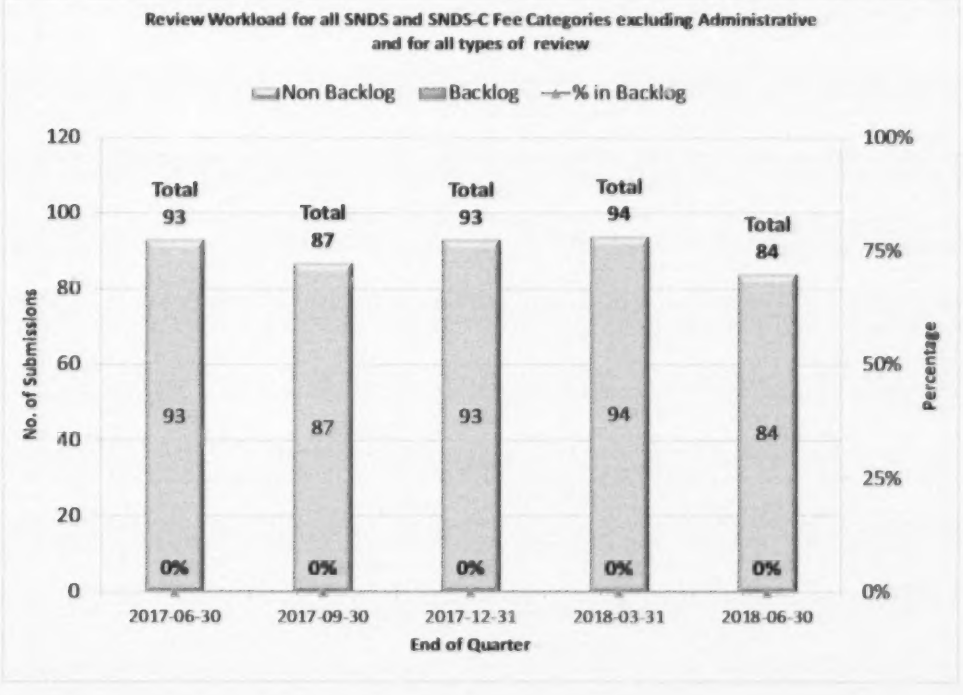
[10] Submissions granted Priority Review Status or found eligible for advance NOC/c consideration are assigned a shortened review target to account for the Priority nature of the submission. For further clarification, please see the Priority Review of Drug Submissions Policy, the Notice of Compliance with conditions (NOC/c) Guidance and the Management of Drug Submissions Guidance.

WORKLOAD

New Drug Submission (NDS) Review Workload / Backlog



Supplemental New Drug Submission (SNDS) Review Workload / Backlog



WORKLOAD

New Drug Submission (NDS) Review Workload by Fee Category

BGTD NDS All REVIEW WORKLOAD BY FEE CATEGORY AND END OF QUARTER					
	2017-06-30	2017-09-30	2017-12-31	2018-03-31	2018-06-30
Clinical or Non-Clin and C&M	**17**	**22**	**21**	**21**	**21**
Backlog	*0*	*0*	*0*	*0*	*0*
New Active Substance	**21**	**18**	**8**	**9**	**12**
Backlog	*0*	*0*	*0*	*0*	*0*
Total	**38**	**40**	**29**	**30**	**33**
Non Backlog	38	40	29	30	33
Backlog	**0**	**0**	**0**	**0**	**0**
% in Backlog	**0%**	**0%**	**0%**	**0%**	**0%**
Priority (subset)	**1**	**1**	**1**	**5**	**7**
Backlog	*0*	*0*	*0*	*0*	*0*

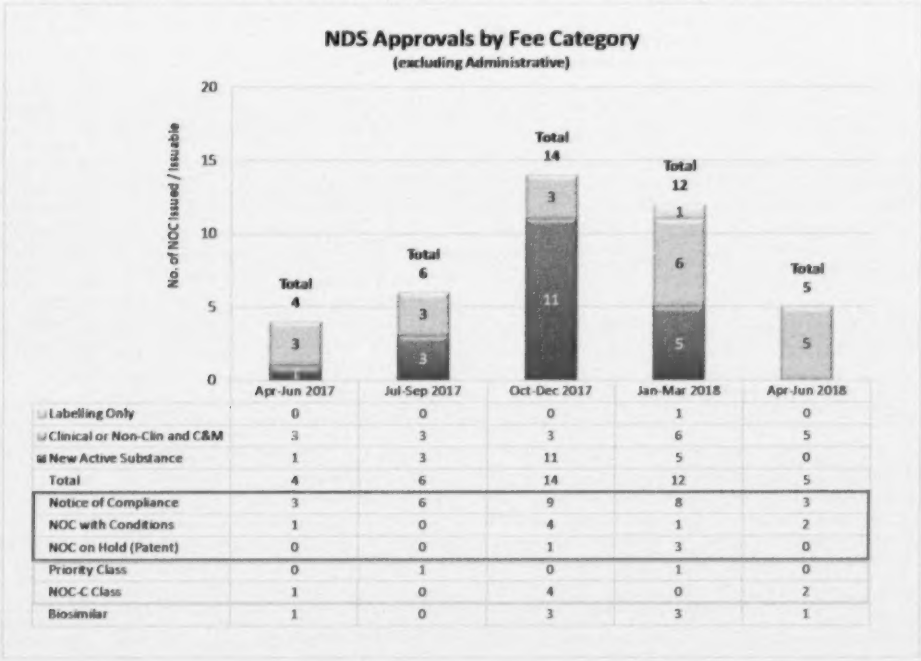
Supplemental New Drug Submission (SNDS) Review Workload by Fee Category

BGTD SNDS All REVIEW WORKLOAD BY FEE CATEGORY AND END OF QUARTER					
	2017-06-30	2017-09-30	2017-12-31	2018-03-31	2018-06-30
Comparative Studies	**2**	**1**	**1**	**1**	**1**
Backlog	*0*	*0*	*0*	*0*	*0*
Chemistry & Manufacturing	**22**	**17**	**23**	**26**	**26**
Backlog	*0*	*0*	*0*	*0*	*0*
Clinical or Non-Clin Only	**45**	**51**	**51**	**54**	**48**
Backlog	*0*	*0*	*0*	*0*	*0*
Clinical or Non-Clin and C&M	**8**	**7**	**6**	**4**	**4**
Backlog	*0*	*0*	*0*	*0*	*0*
Published Data	**4**	**2**	**4**	**2**	**2**
Backlog	*0*	*0*	*0*	*0*	*0*
Labelling Only	**12**	**9**	**8**	**7**	**3**
Backlog	*0*	*0*	*0*	*0*	*0*
Total	**93**	**87**	**93**	**94**	**84**
Non Backlog	93	87	93	94	84
Backlog	**0**	**0**	**0**	**0**	**0**
% in Backlog	**0%**	**0%**	**0%**	**0%**	**0%**
Priority (subset)	**2**	**1**	**0**	**2**	**2**
Backlog	*0*	*0*	*0*	*0*	*0*
SNDS-C (Confirmatory)	**5**	**6**	**6**	**5**	**2**
Backlog	*0*	*0*	*0*	*0*	*0*

APPROVALS

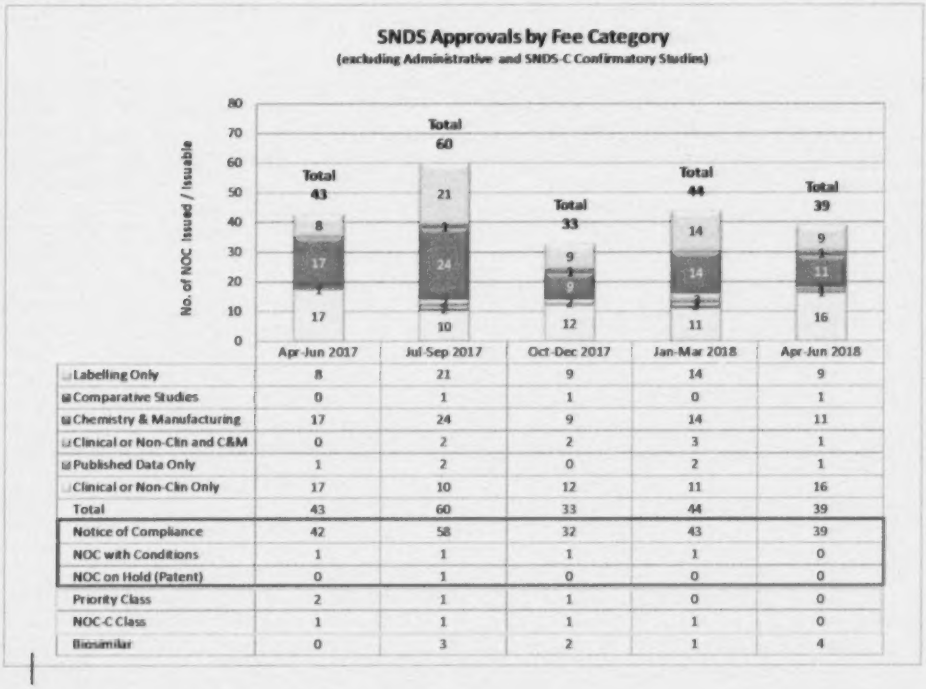
[11]

New Drug Submission (NDS) Approvals by Fee Category and by NOC Type



	Apr-Jun 2017	Jul-Sep 2017	Oct-Dec 2017	Jan-Mar 2018	Apr-Jun 2018
Labelling Only	0	0	0	1	0
Clinical or Non-Clin and C&M	3	3	3	6	5
New Active Substance	1	3	11	5	0
Total	4	6	14	12	5
Notice of Compliance	3	6	9	8	3
NOC with Conditions	1	0	4	1	2
NOC on Hold (Patent)	0	0	1	3	0
Priority Class	0	1	0	1	0
NOC-C Class	1	0	4	0	2
Biosimilar	1	0	3	3	1

Supplemental New Drug Submission (SNDS) Approvals by Fee Category & NOC Type



	Apr-Jun 2017	Jul-Sep 2017	Oct-Dec 2017	Jan-Mar 2018	Apr-Jun 2018
Labelling Only	8	21	9	14	9
Comparative Studies	0	1	1	0	1
Chemistry & Manufacturing	17	24	9	14	11
Clinical or Non-Clin and C&M	0	2	2	3	1
Published Data Only	1	2	0	2	1
Clinical or Non-Clin Only	17	10	12	11	16
Total	43	60	33	44	39
Notice of Compliance	42	58	32	43	39
NOC with Conditions	1	1	1	1	0
NOC on Hold (Patent)	0	1	0	0	0
Priority Class	2	1	1	0	0
NOC-C Class	1	1	1	1	0
Biosimilar	0	3	2	1	4

[11] Submissions granted Priority Review Status or found eligible for advance NOC/c consideration are assigned a shortened review target to account for the Priority nature of the submission. For further clarification, please see the Priority Review of Drug Submissions Policy, the Notice of Compliance with conditions (NOC/c) Guidance and the Management of Drug Submissions Guidance.

Biosimilars: NDS & SNDS Market Authorizations

Biosimilars: Number of NDS & SNDS that were issued an NOC by Quarter

Submission Type	Class	Apr-Jun 2017	Jul-Sep 2017	Oct-Dec 2017	Jan-Mar 2018	Apr-Jun 2018
NDS	CLIN/C&M	1	0	2	0	1
NDS Total		**1**	**0**	**2**	**0**	**1**
SNDS	C&M ONLY	0	1	0	0	1
	C&M/LABELLING	0	0	0	0	0
	CLIN ONLY	0	0	0	0	1
	CLIN/C&M	0	0	0	0	0
	COMP/C&M	0	0	0	0	0
	LABELLING ONLY	0	1	2	1	2
SNDS Total		**0**	**2**	**2**	**1**	**4**

Biosimilars: List of NDS & SNDS issued an NOC – FY 2018-19 by Quarter

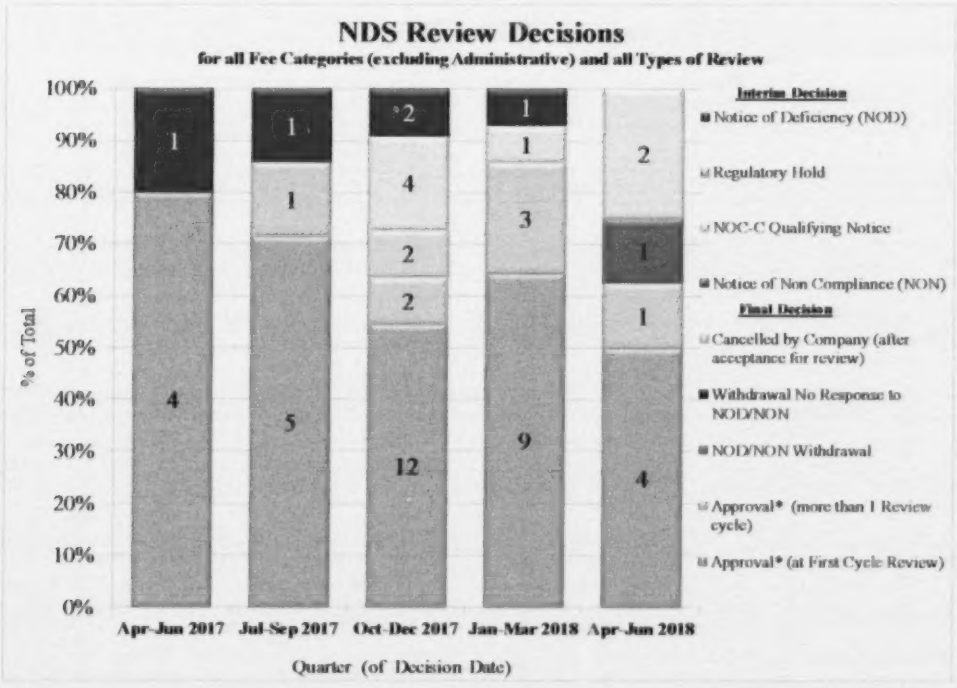
Subm Type	Brand Name	Class	Company	Active Ingredient(s)	Quarter FY 2018-19	Notice of Compliance (NOC) Date
NDS	LAPELGA	CLIN/C&M	APOTEX INC	PEGFILGRASTIM	Q1	2018-Apr-05
New Drug Submission Total						**1**
SNDS	ADMELOG	LABELLING ONLY	SANOFI-AVENTIS CANADA INC.	INSULIN LISPRO	Q1	2018-Apr-30
	BASAGLAR	C&M ONLY	ELI LILLY CANADA INC.	INSULIN GLARGINE	Q1	2018-May-10
	BRENZYS	LABELLING ONLY	SAMSUNG BIOEPIS., LTD.	ETANERCEPT	Q1	2018-Jun-18
	BRENZYS (PFP), BRENZYS (PFS)	CLIN ONLY	SAMSUNG BIOEPIS., LTD.	ETANERCEPT	Q1	2018-Jun-14
Supplemental New Drug Submission Total						**4**

Please note: Approved Biosimilars that remain on Intellectual Property Hold are not included.

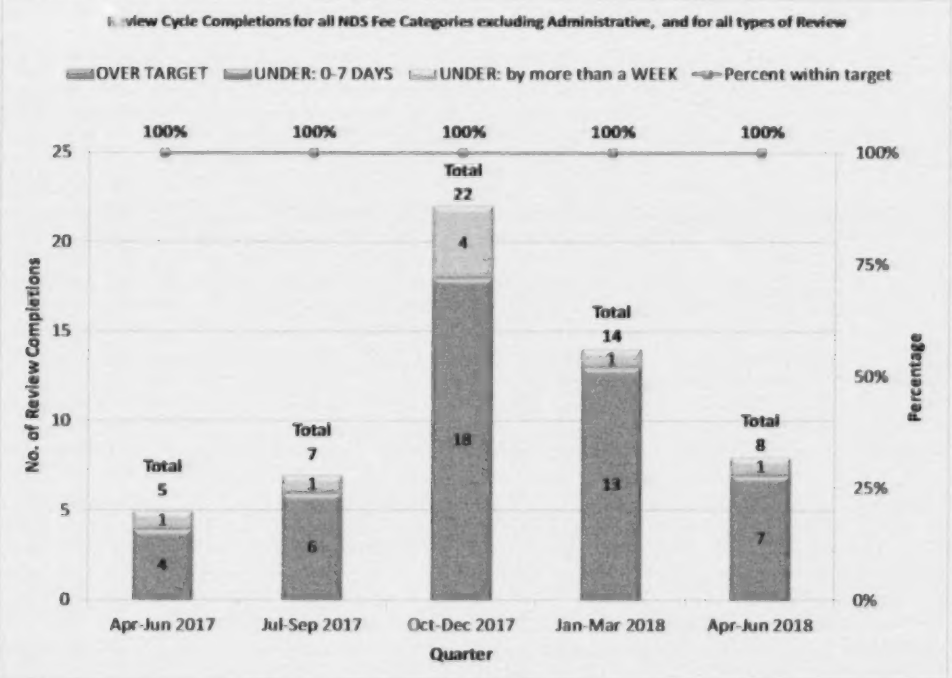
Biosimilar: A biologic drug that enters the market subsequent to a version previously authorized in Canada, and with demonstrated similarity to a reference biologic drug. Biosimilar relies in part on prior information regarding safety and efficacy that is deemed relevant due to the demonstration of similarity to the reference biologic drug and which influences the amount and type of original data required

REVIEW CYCLE DECISIONS

New Drug Submission (NDS) Review Decisions

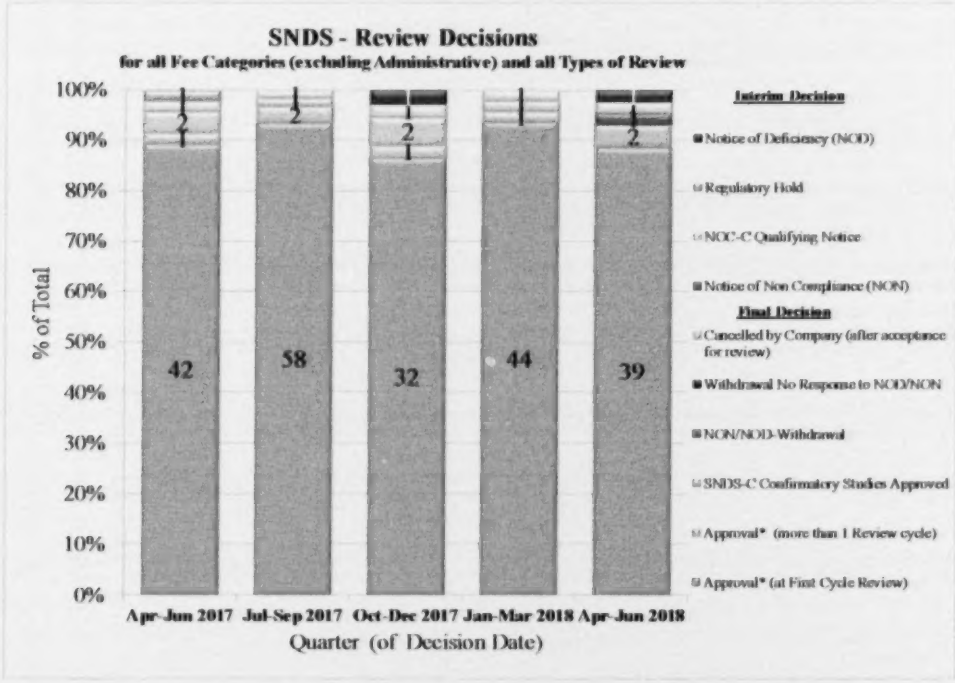


NDS - Review Cycle Completions Showing Percentage Within Target

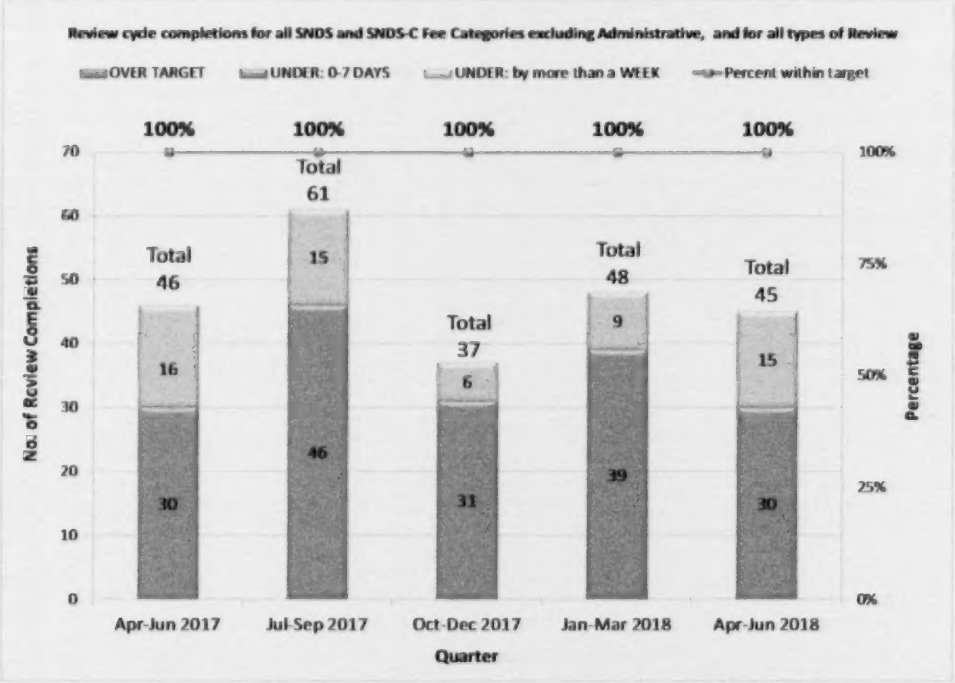


REVIEW CYCLE DECISIONS

Supplemental New Drug Submission (SNDS) Review Decisions

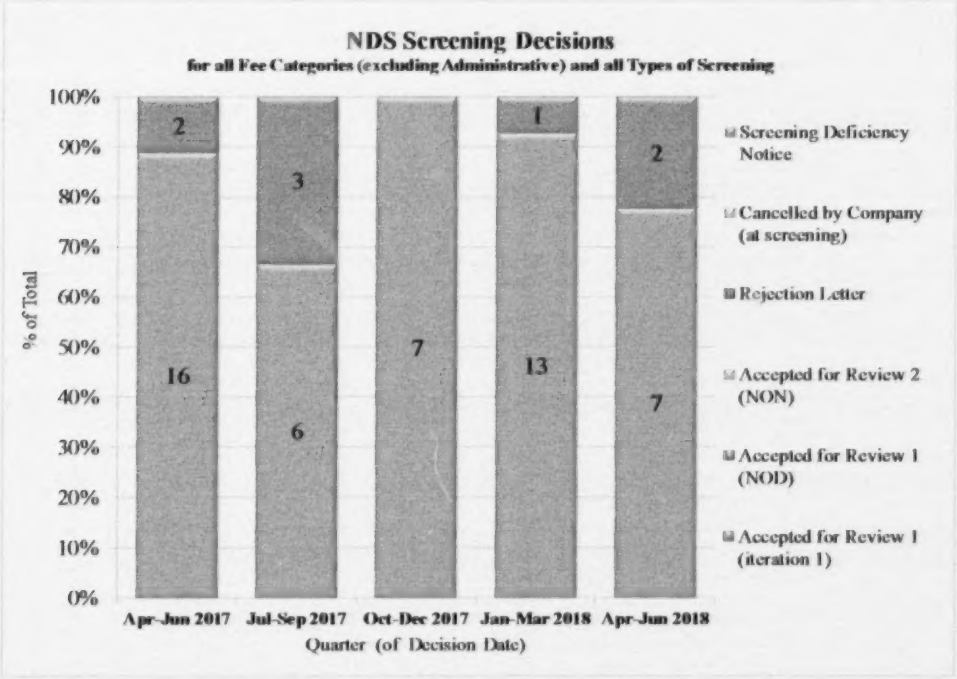


SNDS - Review Cycle Completions Showing Percentage Within Target

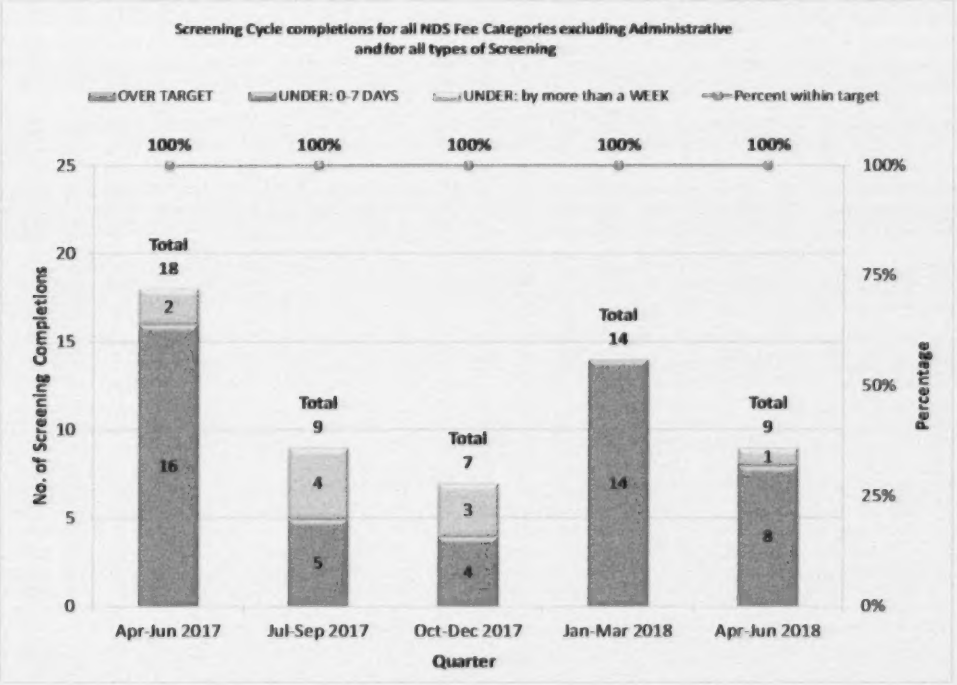


SCREENING CYCLE DECISIONS

New Drug Submission (NDS) Screening Decisions

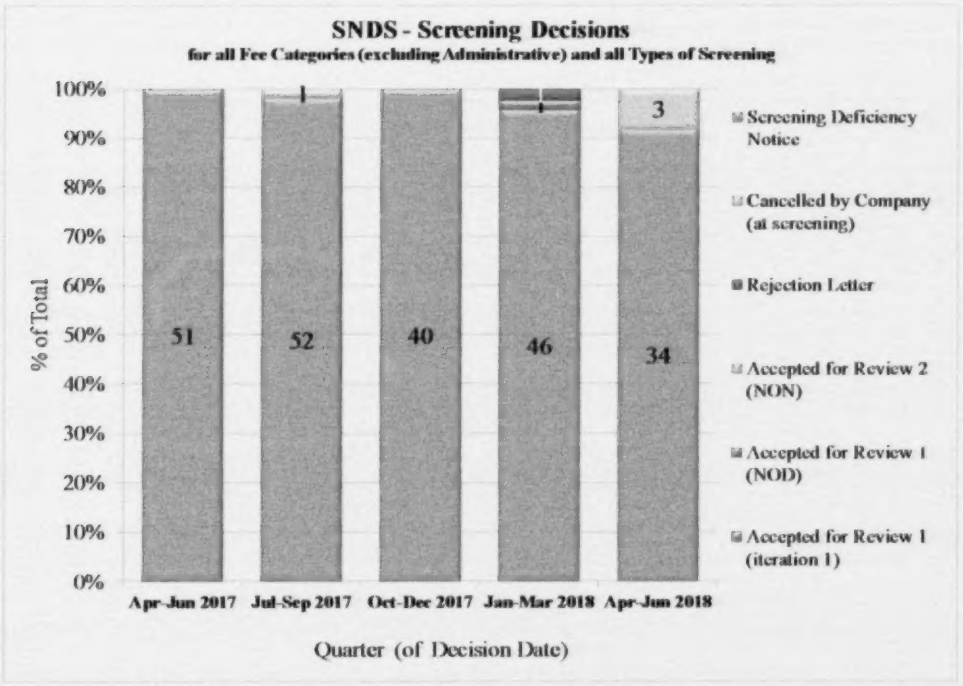


NDS - Screening Cycle Completions Showing Percentage Within Target

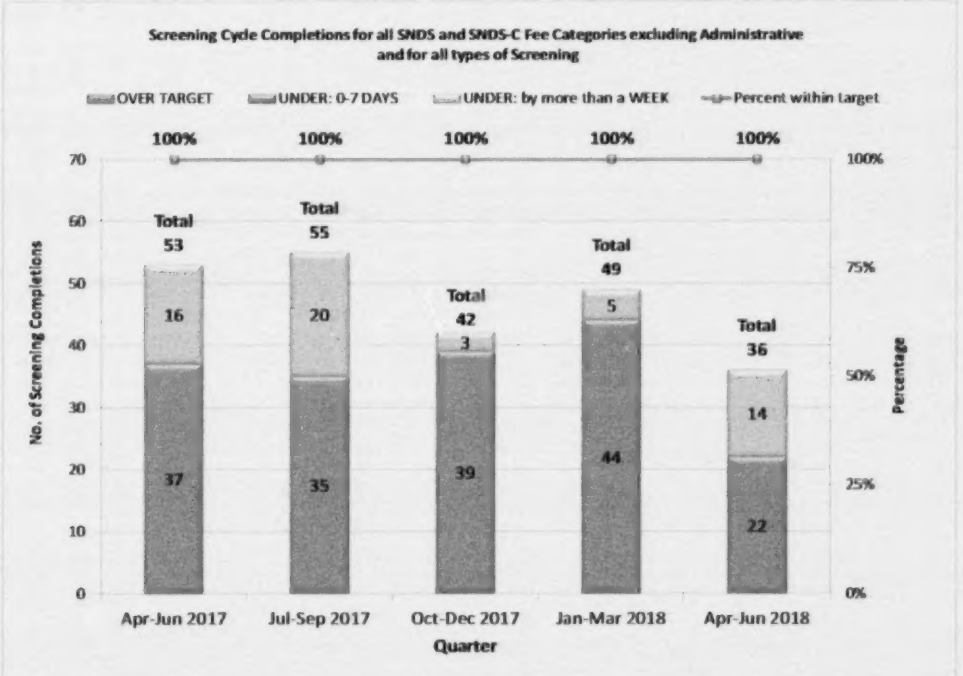


SCREENING CYCLE DECISIONS

Supplemental New Drug Submission (SNDS) Screening Decisions

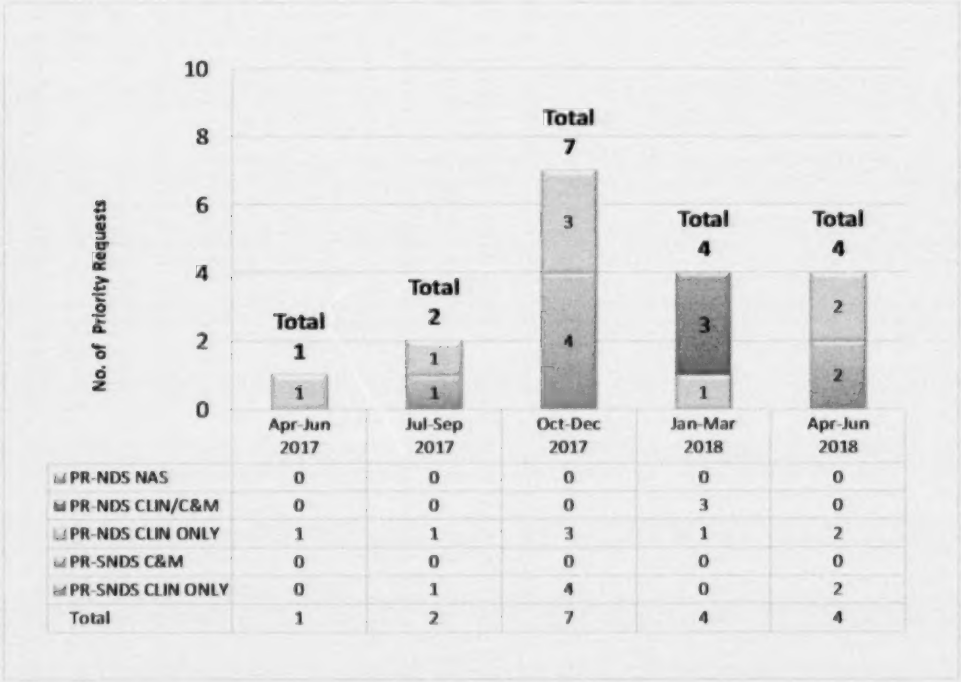


SNDS - Screening Cycle Completions Showing Percentage Within Target



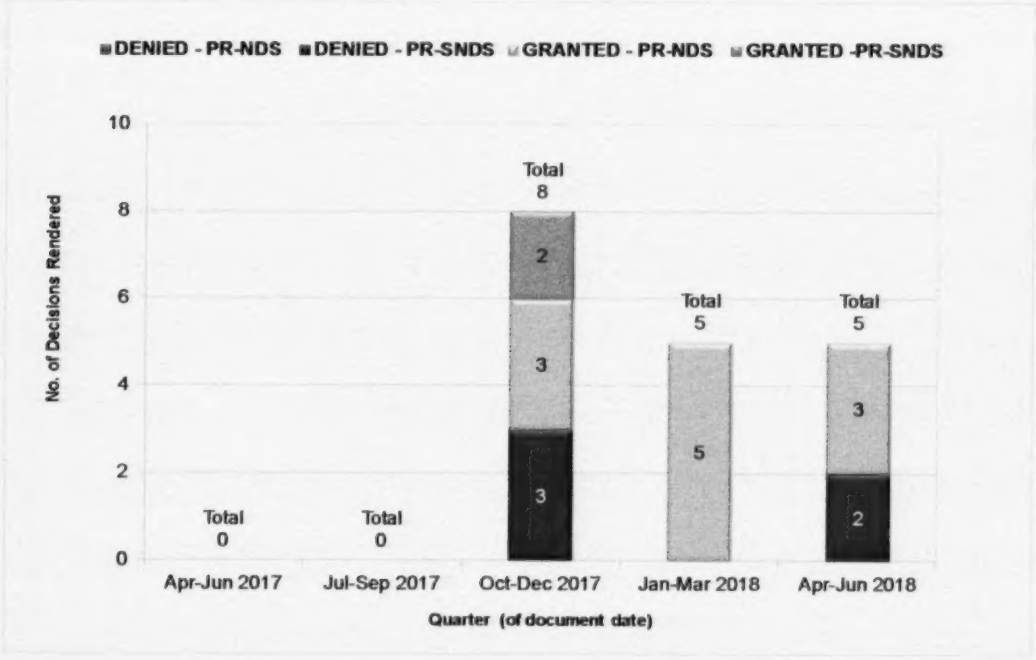
Priority Review Status Requests (for NDS & SNDS)

Priority Review Status Requests Received

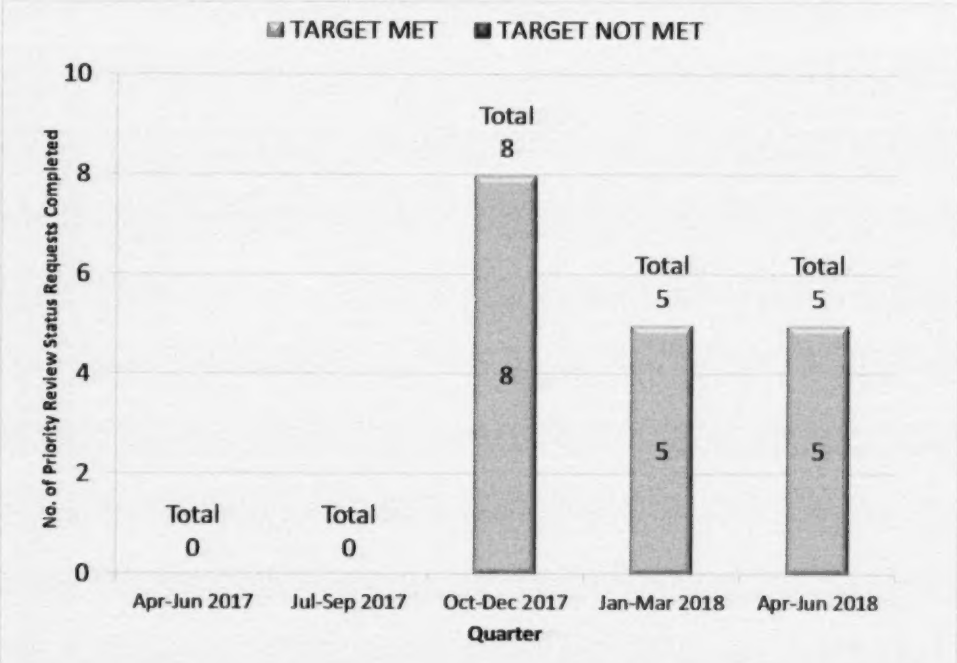


	Apr-Jun 2017	Jul-Sep 2017	Oct-Dec 2017	Jan-Mar 2018	Apr-Jun 2018
PR-NDS NAS	0	0	0	0	0
PR-NDS CLIN/C&M	0	0	0	3	0
PR-NDS CLIN ONLY	1	1	3	1	2
PR-SNDS C&M	0	0	0	0	0
PR-SNDS CLIN ONLY	0	1	4	0	2
Total	1	2	7	4	4

Priority Review Status Requests: Decisions Rendered



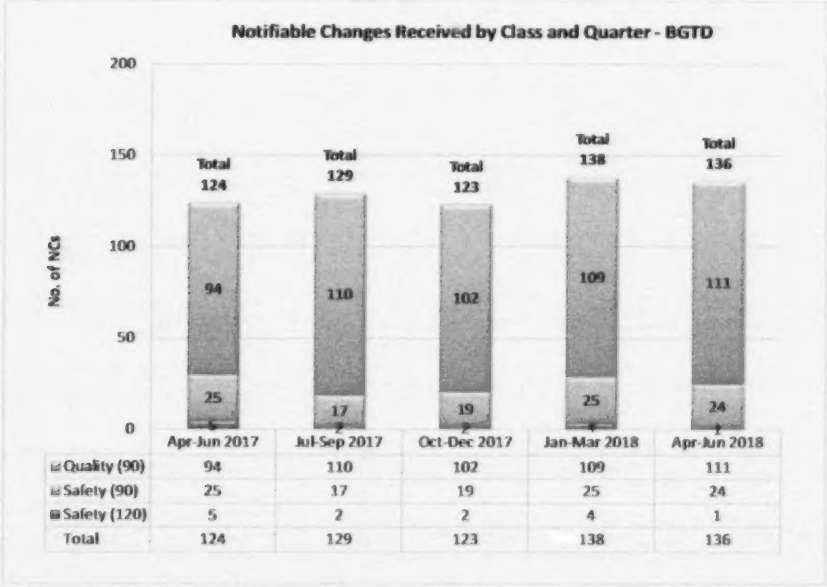
Priority Review Status Request: Performance



Notifiable Changes (NC)

NOTIFIABLE CHANGE

Submissions Received - Notifiable Change (NC)



	Apr-Jun 2017	Jul-Sep 2017	Oct-Dec 2017	Jan-Mar 2018	Apr-Jun 2018
Quality (90)	94	110	102	109	111
Safety (90)	25	17	19	25	24
Safety (120)	5	2	2	4	1
Total	124	129	123	138	136

Decision Documents by Class - Notifiable Change (NC)

NC - SAFETY (90)					
DOCUMENT TYPE	**Apr-Jun 2017**	**Jul-Sep 2017**	**Oct-Dec 2017**	**Jan-Mar 2018**	**Apr-Jun 2018**
NO OBJECTION LETTER	30	19	17	22	25
REJECTION LETTER (SCR)	0	0	0	0	0
CANCELLED BY COMPANY	2	1	2	1	2
SCREENING DEFICIENCY NOTICE	0	1	0	0	0
NOT SATISFACTORY NOTICE	0	0	0	0	0
NC - HOLD (PATENT)	0	0	0	0	0

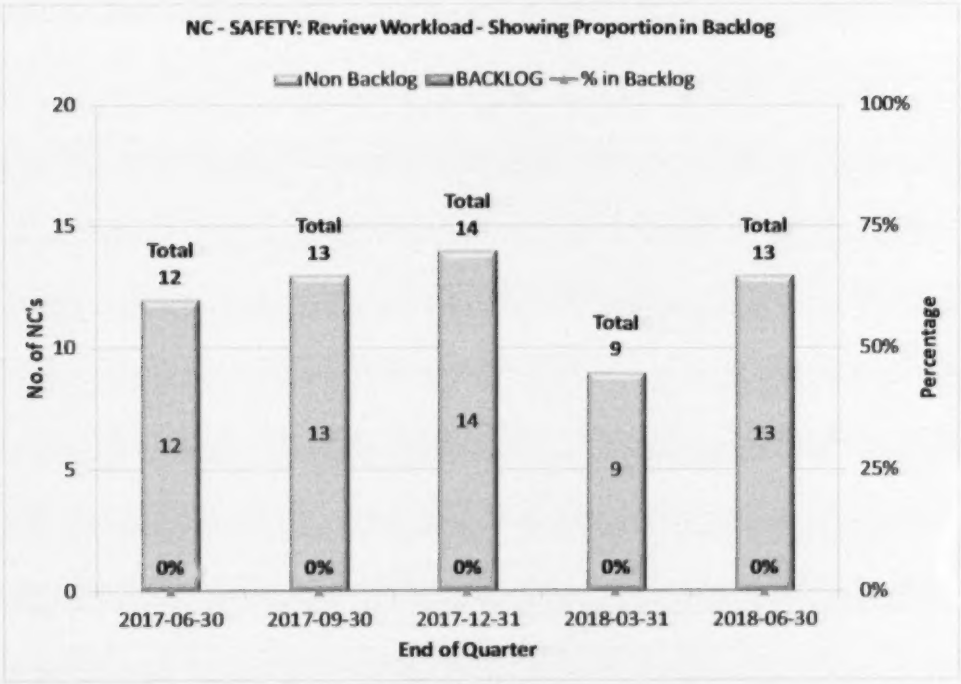
NC - QUALITY (90)					
DOCUMENT TYPE	**Apr-Jun 2017**	**Jul-Sep 2017**	**Oct-Dec 2017**	**Jan-Mar 2018**	**Apr-Jun 2018**
NO OBJECTION LETTER	85	103	108	85	117
NOT SATISFACTORY NOTICE	0	0	0	0	0
REJECTION LETTER (SCR)	0	0	1	11	2
SCREENING DEFICIENCY NOTICE	1	1	0	0	0
CANCELLED BY COMPANY	4	2	2	0	4

NC - SAFETY (120)					
DOCUMENT TYPE	**Apr-Jun 2017**	**Jul-Sep 2017**	**Oct-Dec 2017**	**Jan-Mar 2018**	**Apr-Jun 2018**
NO OBJECTION LETTER	8	0	2	2	1
NOT SATISFACTORY NOTICE	0	0	0	0	0
REJECTION LETTER (SCR)	0	0	0	0	0
SCREENING DEFICIENCY NOTICE	1	0	0	0	0
CANCELLED BY COMPANY	1	0	1	0	1

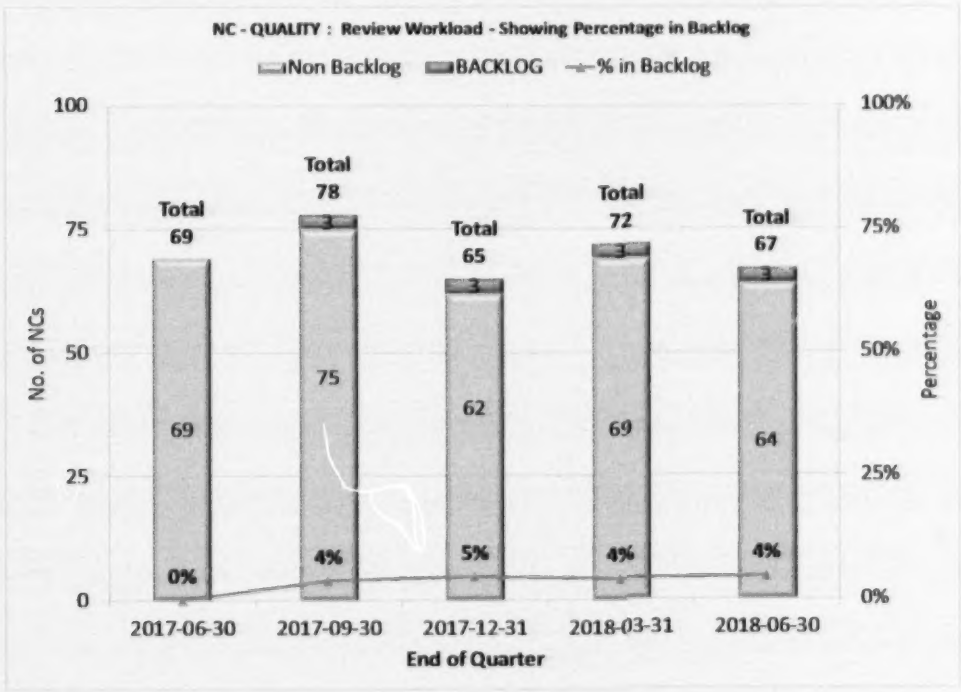
NC - ADMINISTRATIVE					
DOCUMENT TYPE	**Apr-Jun 2017**	**Jul-Sep 2017**	**Oct-Dec 2017**	**Jan-Mar 2018**	**Apr-Jun 2018**
NO OBJECTION LETTER	2	0	3	4	2
CANCELLED BY COMPANY	0	0	0	0	0

WORKLOAD

Notifiable Change (NC) SAFETY - Review Workload / Backlog



Notifiable Change (NC) QUALITY - Review Workload / Backlog



WORKLOAD

Notifiable Change (NC) SAFETY - Review Workload by Class

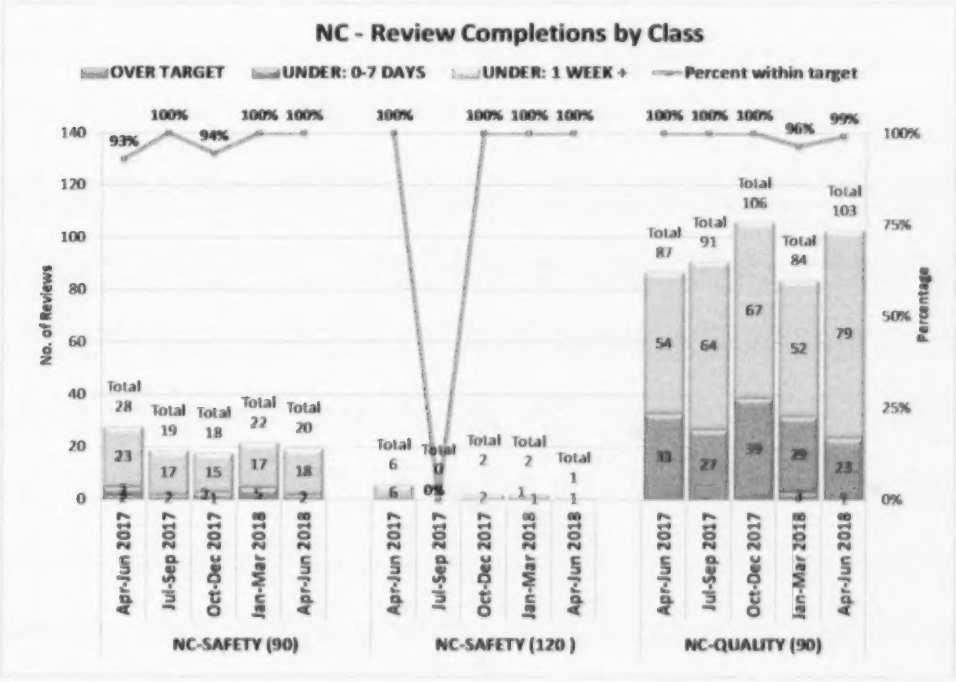
BGTD NC - SAFETY: REVIEW WORKLOAD AT END OF QUARTER					
FEE Category	2017-06-30	2017-09-30	2017-12-31	2018-03-31	2018-06-30
SAFETY - 90 day	**12**	**11**	**13**	**8**	**11**
Backlog	*0*	*0*	*0*	*0*	*0*
SAFETY - 120 day	**0**	**2**	**1**	**1**	**2**
Backlog	*0*	*0*	*0*	*0*	*0*
Total	**12**	**13**	**14**	**9**	**13**
Non Backlog	12	13	14	9	13
BACKLOG	**0**	**0**	**0**	**0**	**0**
% in Backlog	**0%**	**0%**	**0%**	**0%**	**0%**

Notifiable Change (NC) QUALITY - Review Workload by Class

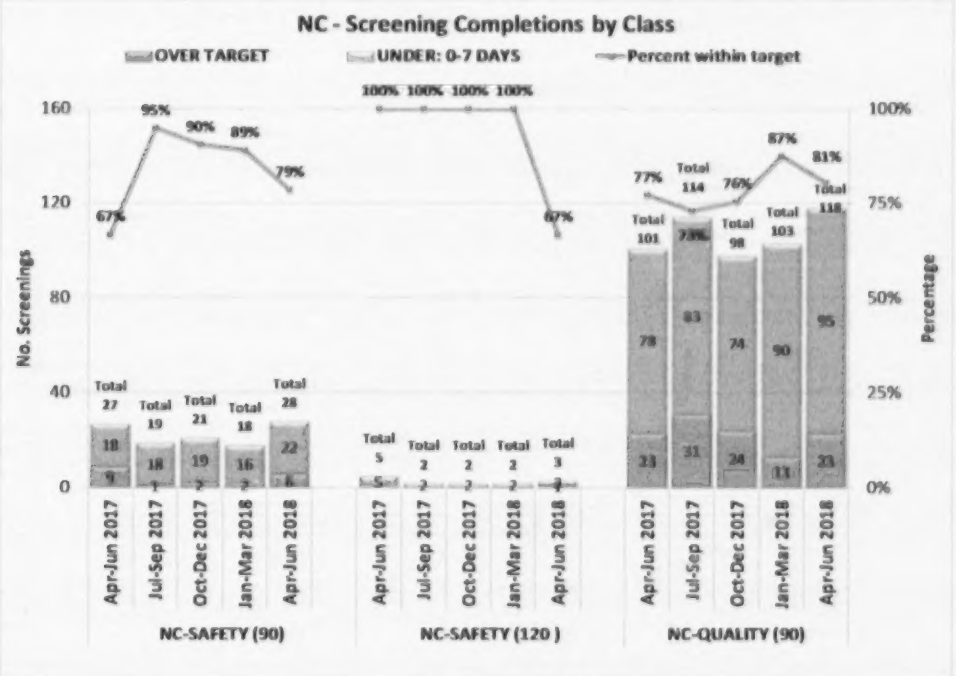
BGTD NC - QUALITY: REVIEW WORKLOAD AT END OF QUARTER					
CLASS	2017-06-30	2017-09-30	2017-12-31	2018-03-31	2018-06-30
QUALITY - 90 day	**69**	**78**	**65**	**72**	**67**
Backlog	*0*	*3*	*3*	*3*	*3*
Total	**69**	**78**	**65**	**72**	**67**
Non Backlog	69	75	62	69	64
BACKLOG	**0**	3	3	3	3
% in Backlog	**0%**	4%	5%	4%	4%

PERFORMANCE

REVIEW Completions by Class - Notifiable Change (NC)



SCREENING Completions by Class - Notifiable Changes (NC)



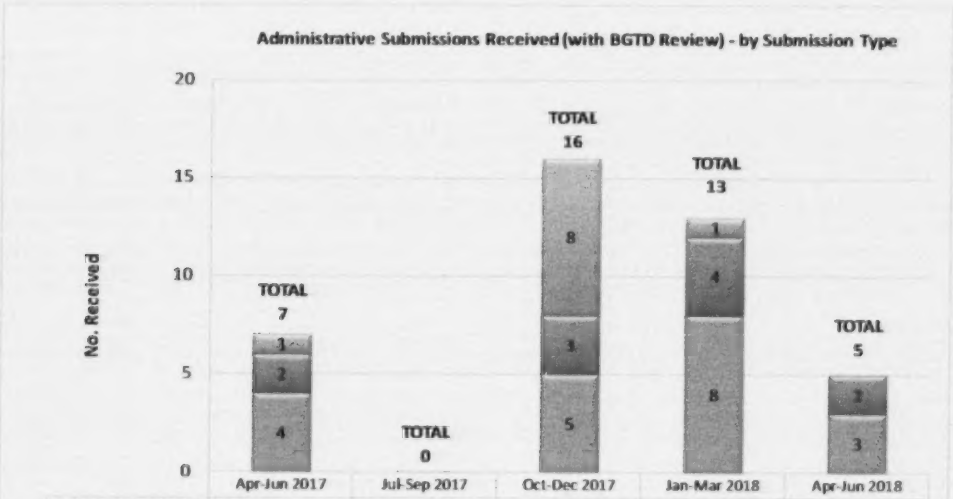
Administrative Submissions

Submissions in support of a manufacturer or product name change.

ADMINISTRATIVE SUBMISSIONS (with BGTD Review)

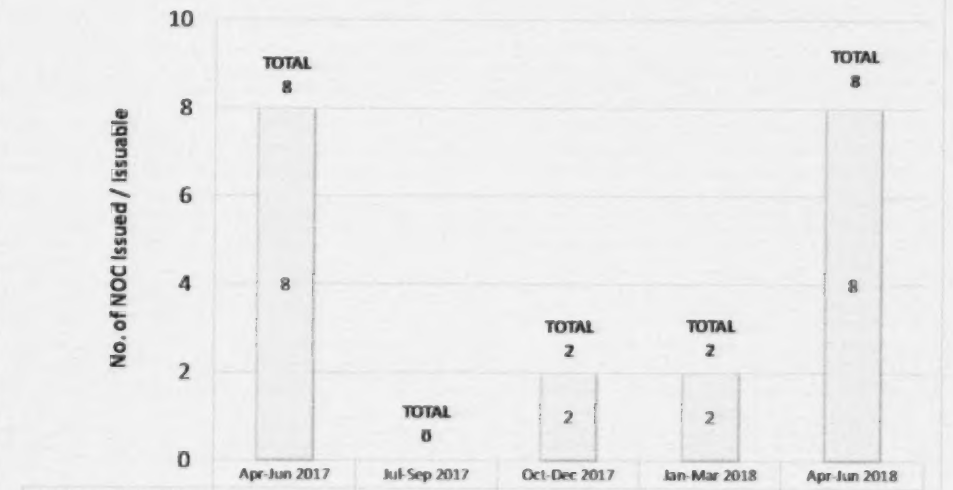
(such as product name change that requires a drug name review)

Administrative Submissions Received (with BGTD Review)



	Apr-Jun 2017	Jul-Sep 2017	Oct-Dec 2017	Jan-Mar 2018	Apr-Jun 2018
DINB Administrative	1	0	8	1	0
NC Administrative	2	0	3	4	2
NDS Administrative	4	0	5	8	3
SNDS Administrative	0	0	0	0	0
TOTAL	7	0	16	13	5

Administrative Submission Approvals (with BGTD Review)

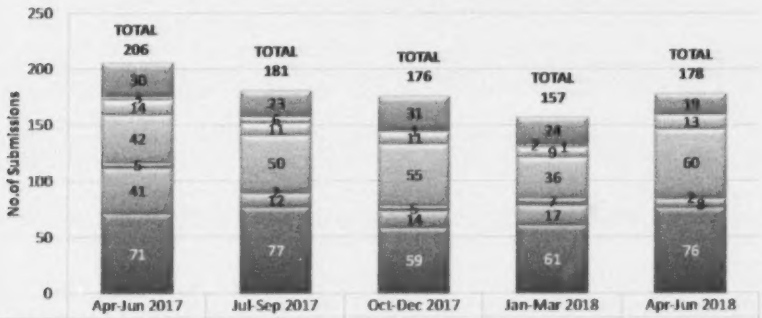


	Apr-Jun 2017	Jul-Sep 2017	Oct-Dec 2017	Jan-Mar 2018	Apr-Jun 2018
NDS - ADMINISTRATIVE	8	0	2	2	8
SNDS - ADMINISTRATIVE	0	0	0	0	0
TOTAL	8	0	2	2	8

ADMINISTRATIVE SUBMISSIONS (Processed by OSIP)

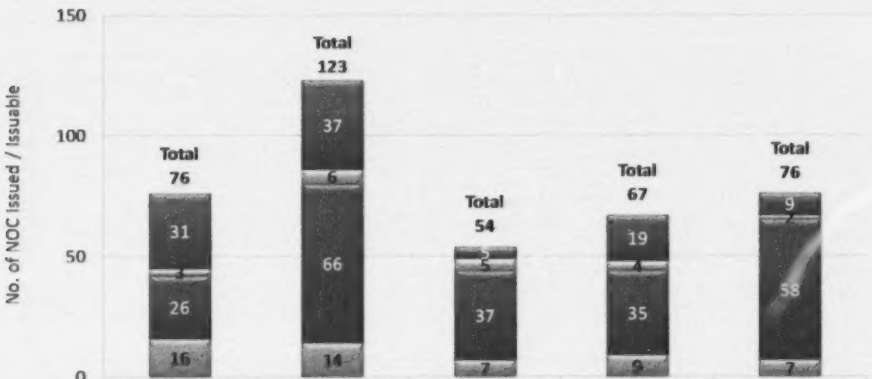
(Product & Manufacturer Name Changes) (Admin NCs are for cross-referenced changes)

Administrative Submissions Received by Submission Type (OSIP)



	Apr-Jun 2017	Jul-Sep 2017	Oct-Dec 2017	Jan-Mar 2018	Apr-Jun 2018
DINA	30	23	31	24	19
DINF	3	6	0	2	0
DINB	0	0	0	0	0
DIND	0	0	0	0	0
PDC	0	0	1	1	0
SANDS	14	11	11	9	13
ANDS	42	50	55	36	60
SNDS	5	2	5	7	2
NDS	41	12	14	17	8
NC	71	77	59	61	76
TOTAL	206	181	176	157	178

Administrative Submission Approvals (OSIP) - for NDS, SNDS, ANDS and SANDS



	Apr-Jun 2017	Jul-Sep 2017	Oct-Dec 2017	Jan-Mar 2018	Apr-Jun 2018
NDS	31	37	5	19	9
SNDS	3	6	5	4	2
ANDS	26	66	37	35	58
SANDS	16	14	7	9	7
Total	76	123	54	67	76

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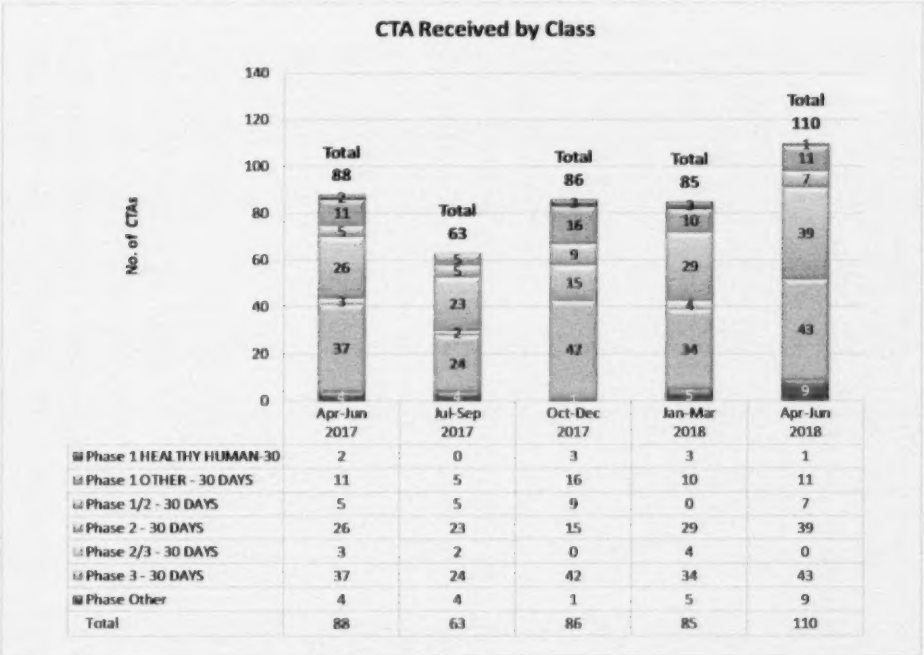
Clinical Trial Applications and Amendments

(CTA & CTA-A)

Clinical Trial Applications (CTA)

Number Received - Clinical Trial Application (CTA)

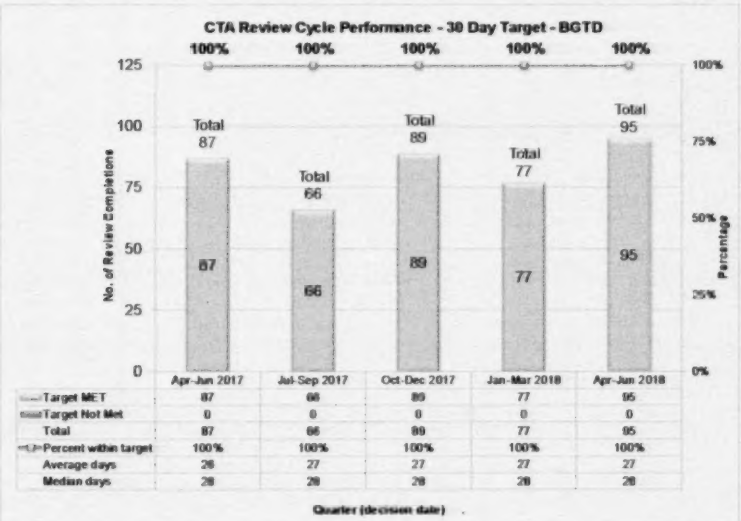


	Apr-Jun 2017	Jul-Sep 2017	Oct-Dec 2017	Jan-Mar 2018	Apr-Jun 2018
Phase 1 HEALTHY HUMAN-30	2	0	3	3	1
Phase 1 OTHER - 30 DAYS	11	5	16	10	11
Phase 1/2 - 30 DAYS	5	5	9	0	7
Phase 2 - 30 DAYS	26	23	15	29	39
Phase 2/3 - 30 DAYS	3	2	0	4	0
Phase 3 - 30 DAYS	37	24	42	34	43
Phase Other	4	4	1	5	9
Total	88	63	86	85	110

Decision Documents - Clinical Trial Application (CTA)

CTA					
DOCUMENT TYPE	Apr-Jun 2017	Jul-Sep 2017	Oct-Dec 2017	Jan-Mar 2018	Apr-Jun 2018
NO OBJECTION LETTER	84	63	85	75	92
CANCELLED BY COMPANY	4	3	6	5	3
NOT SATISFACTORY NOTICE	0	0	0	0	0
REJECTION LETTER (SCR)	0	0	0	0	0

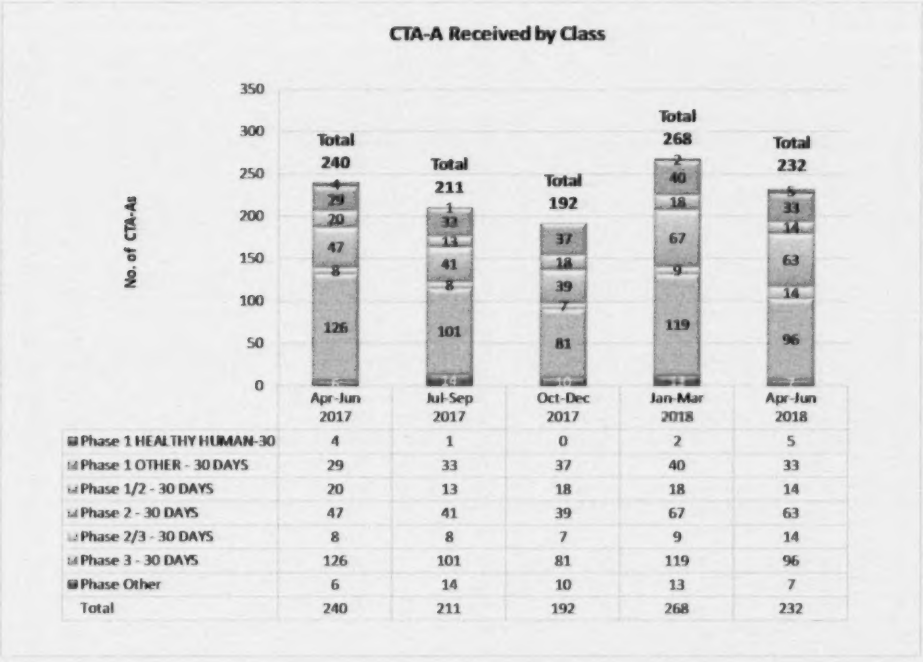
Performance – Clinical Trial Applications (CTA) Reviews - 30 Day Target



	Apr-Jun 2017	Jul-Sep 2017	Oct-Dec 2017	Jan-Mar 2018	Apr-Jun 2018
Target MET	87	66	89	77	95
Target Not Met	0	0	0	0	0
Total	87	66	89	77	95
Percent within target	100%	100%	100%	100%	100%
Average days	26	27	27	27	27
Median days	28	28	28	28	28

Clinical Trial Application- Amendments (CTA-A)

Number Received - Clinical Trial Application Amendments (CTA-A)

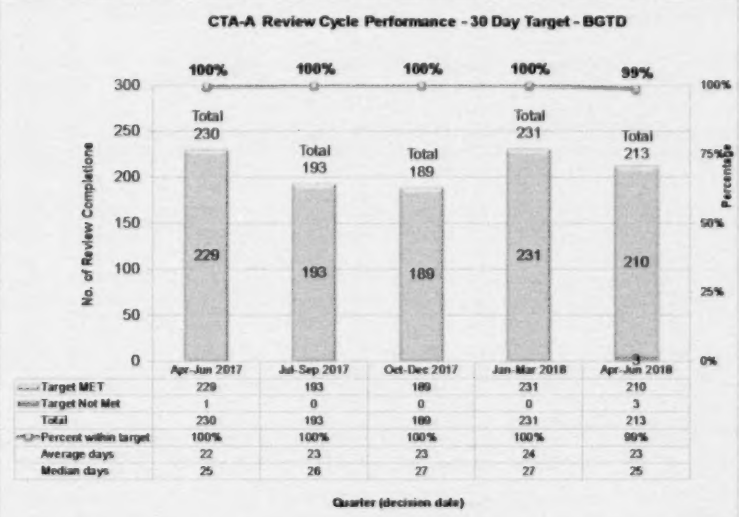


	Apr-Jun 2017	Jul-Sep 2017	Oct-Dec 2017	Jan-Mar 2018	Apr-Jun 2018
Phase 1 HEALTHY HUMAN-30	4	1	0	2	5
Phase 1 OTHER - 30 DAYS	29	33	37	40	33
Phase 1/2 - 30 DAYS	20	13	18	18	14
Phase 2 - 30 DAYS	47	41	39	67	63
Phase 2/3 - 30 DAYS	8	8	7	9	14
Phase 3 - 30 DAYS	126	101	81	119	96
Phase Other	6	14	10	13	7
Total	240	211	192	268	232

Decision Documents - Clinical Trial Application Amendments (CTA-A)

CTA-A					
DOCUMENT TYPE	**Apr-Jun 2017**	**Jul-Sep 2017**	**Oct-Dec 2017**	**Jan-Mar 2018**	**Apr-Jun 2018**
NO OBJECTION LETTER	268	193	202	240	228
REJECTION LETTER (SCR)	4	4	3	4	7
CANCELLED BY COMPANY	3	14	2	5	1
NOT SATISFACTORY NOTICE	0	0	0	0	0

Performance – CTA-A Reviews - 30 Day Target



	Apr-Jun 2017	Jul-Sep 2017	Oct-Dec 2017	Jan-Mar 2018	Apr-Jun 2018
Target MET	229	193	189	231	210
Target Not Met	1	0	0	0	3
Total	230	193	189	231	213
Percent within target	100%	100%	100%	100%	99%
Average days	22	23	23	24	23
Median days	25	26	27	27	25

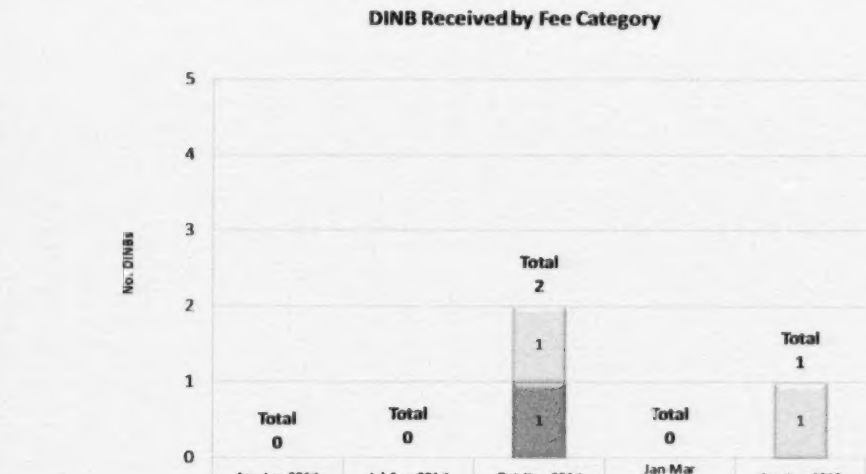
DINB

Application for a Drug Identification Number

Biological Product

DINB: Application for a Drug Identification Number – BIOLOGICAL PRODUCT

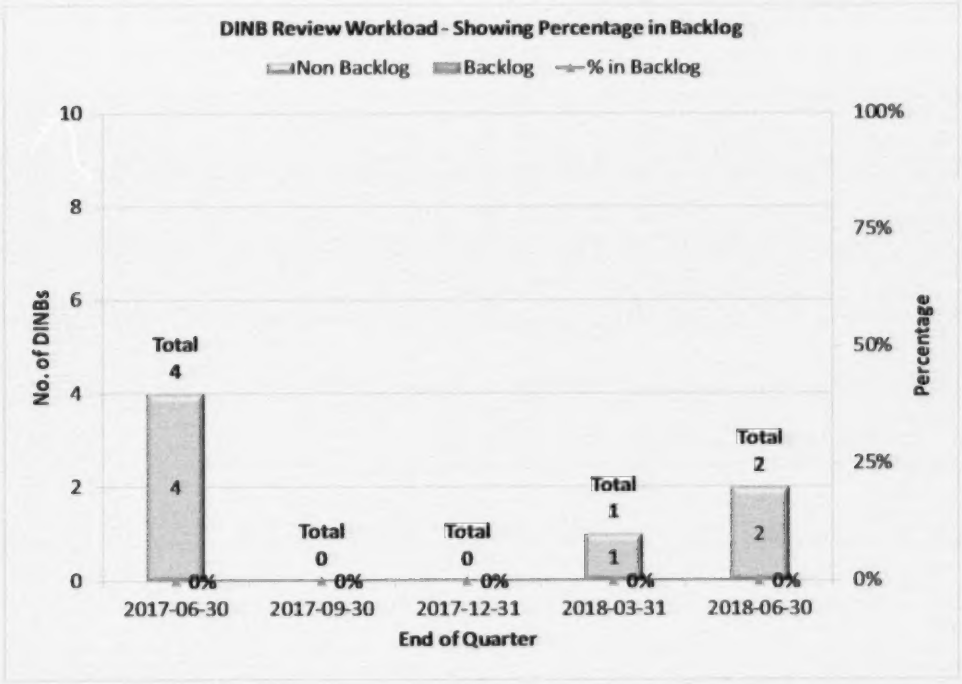
Number Received - DINB



	Apr Jun 2017	Jul Sep 2017	Oct Dec 2017	Jan Mar 2018	Apr Jun 2018
Labelling Only	0	0	1	0	1
Chemistry & Manufacturing	0	0	1	0	0
Comparative Studies	0	0	0	0	0
Clinical or Non-Clin Only	0	0	0	0	0
Clinical or Non-Clin and C&M	0	0	0	0	0
Total	0	0	2	0	1

REVIEW WORKLOAD

Review Workload / Backlog - Showing Percentage in Backlog - DINB

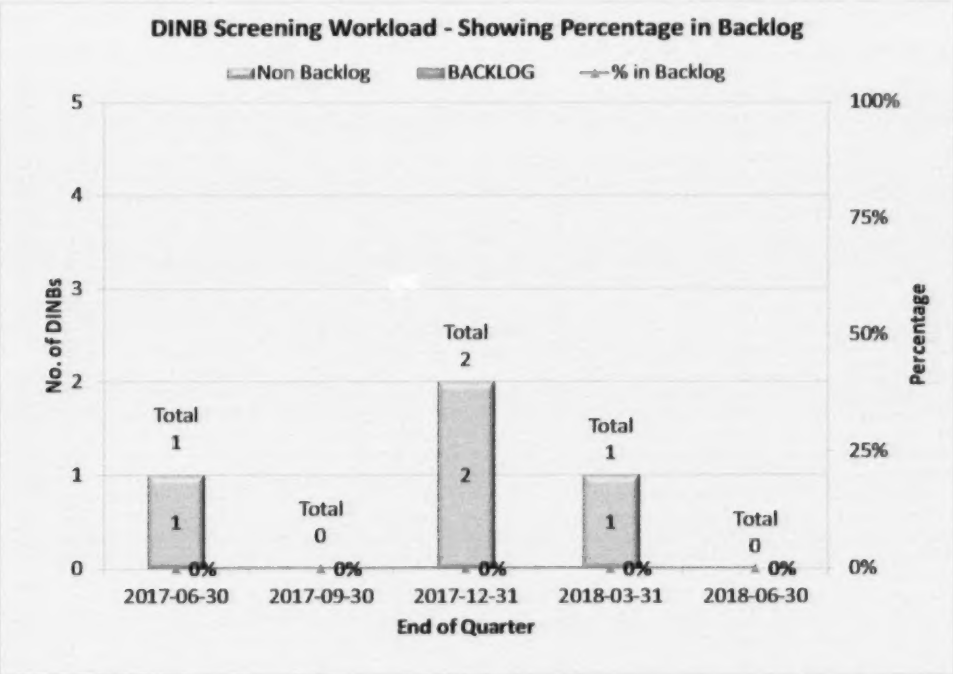


Review Workload by Class - DINB

BGTD DINB All REVIEW WORKLOAD BY FEE CATEGORY AND END OF QUARTER					
	2017-06-30	2017-09-30	2017-12-31	2018-03-31	2018-06-30
Labelling Only	**2**	**0**	**0**	**1**	**1**
Backlog	*0*	*0*	*0*	*0*	*0*
Chemistry & Manufacturing	**2**	**0**	**0**	**0**	**1**
Backlog	*0*	*0*	*0*	*0*	*0*
Total	**4**	**0**	**0**	**1**	**2**
Non Backlog	4	0	0	1	2
Backlog	**0**	**0**	**0**	**0**	**0**
% in Backlog	**0%**	**0%**	**0%**	**0%**	**0%**

SCREENING WORKLOAD

Screening Workload / Backlog - Showing Percentage in Backlog - DINB



Screening Workload by Class - DINB

BGTD DINB All SCREENING WORKLOAD BY FEE CATEGORY AND END OF QUARTER					
	2017-06-30	2017-09-30	2017-12-31	2018-03-31	2018-06-30
Labelling Only	**0**	**0**	**1**	**0**	**0**
Backlog	*0*	*0*	*0*	*0*	*0*
Chemistry & Manufacturing	**1**	**0**	**1**	**1**	**0**
Backlog	*0*	*0*	*0*	*0*	*0*
Total	**1**	**0**	**2**	**1**	**0**
Non Backlog	1	0	2	1	*0*
BACKLOG	**0**	**0**	**0**	**0**	**0**
% in Backlog	**0%**	**0%**	**0%**	**0%**	**0%**

DECISION DOCUMENTS

Decision Documents – DINB by Class

DINB - Labelling Only					
DOCUMENT TYPE	**Apr-Jun 2017**	**Jul-Sep 2017**	**Oct-Dec 2017**	**Jan-Mar 2018**	**Apr-Jun 2018**
NO OBJECTION LETTER	0	0	0	0	0
SCREENING DEFICIENCY NOTICE	0	0	0	0	0
CANCELLED BY COMPANY	4	2	0	0	0

DINB - CLINICAL OR NON CLINICAL DATA AND C&M					
DOCUMENT TYPE	**Apr-Jun 2017**	**Jul-Sep 2017**	**Oct-Dec 2017**	**Jan-Mar 2018**	**Apr-Jun 2018**
SCREENING DEFICIENCY NOTICE	0	0	0	0	0
CANCELLED BY COMPANY	0	0	0	0	0

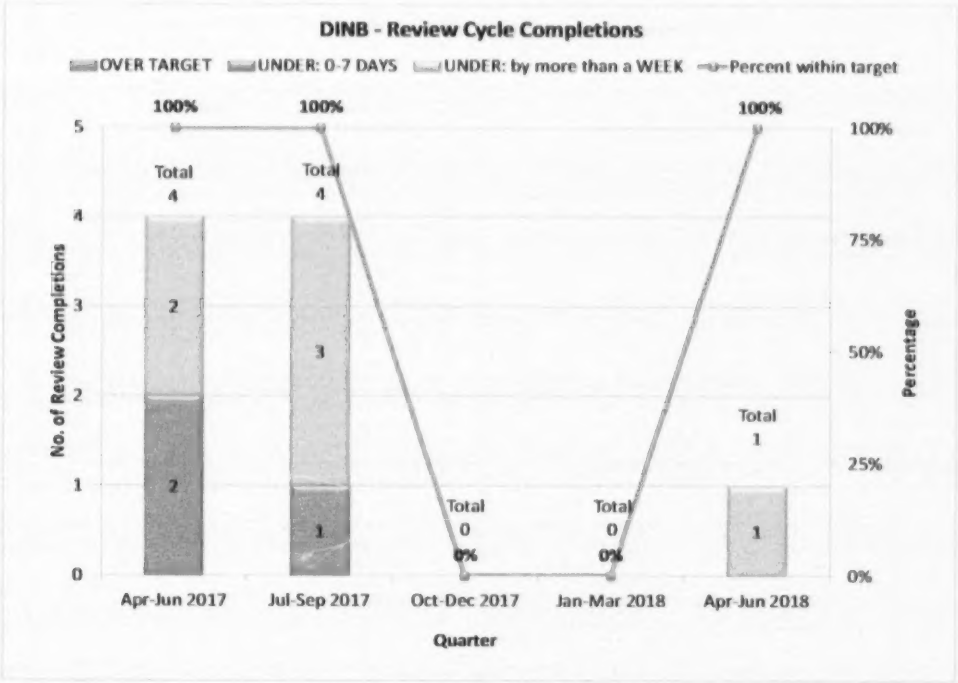
DINB - CHEMISTRY & MANUFACTURING					
DOCUMENT TYPE	**Apr-Jun 2017**	**Jul-Sep 2017**	**Oct-Dec 2017**	**Jan-Mar 2018**	**Apr-Jun 2018**
NO OBJECTION LETTER	0	0	0	0	0
SCREENING DEFICIENCY NOTICE	0	0	0	1	0
NOTICE OF DEFICIENCY	0	0	0	0	0
NOTIFICATION FORM/DIN ISSUED	0	1	0	0	0
CANCELLED BY COMPANY	0	0	0	0	0

DINB - COMPARATIVE STUDIES					
DOCUMENT TYPE	**Apr-Jun 2017**	**Jul-Sep 2017**	**Oct-Dec 2017**	**Jan-Mar 2018**	**Apr-Jun 2018**
SCREENING DEFICIENCY NOTICE	0	0	0	0	0
REJECTION LETTER (SCR)	0	0	0	0	0

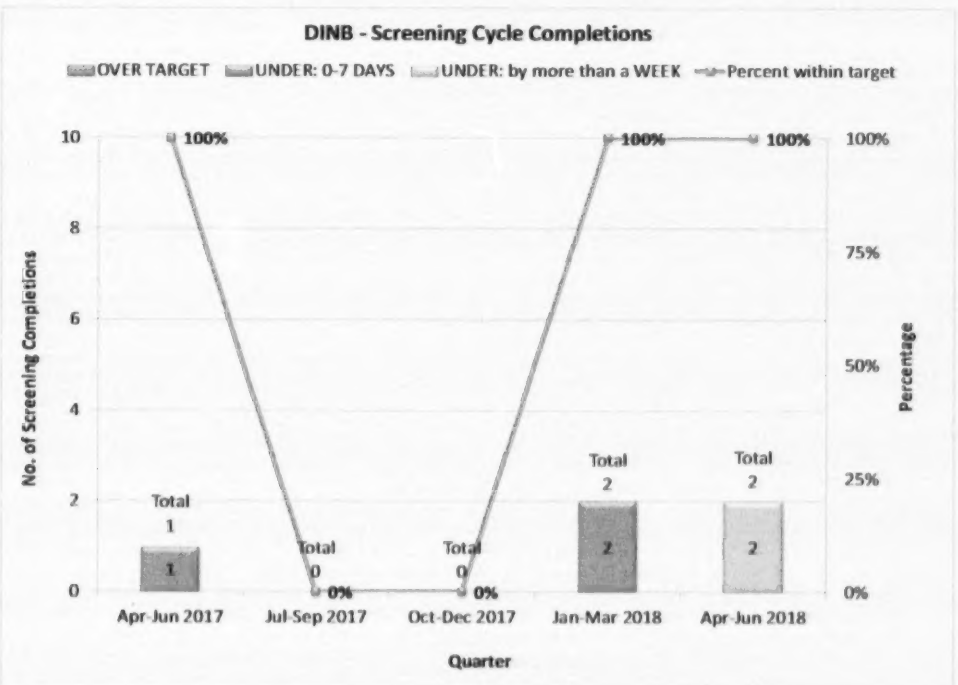
DINB - Administrative					
DOCUMENT TYPE	**Apr-Jun 2017**	**Jul-Sep 2017**	**Oct-Dec 2017**	**Jan-Mar 2018**	**Apr-Jun 2018**
NOTIFICATION FORM/DIN ISSUED	0	0	0	0	0
CANCELLED BY COMPANY	0	0	1	0	0

PERFORMANCE

Performance Review Cycle Completions Showing Percentage Within Target - DINB

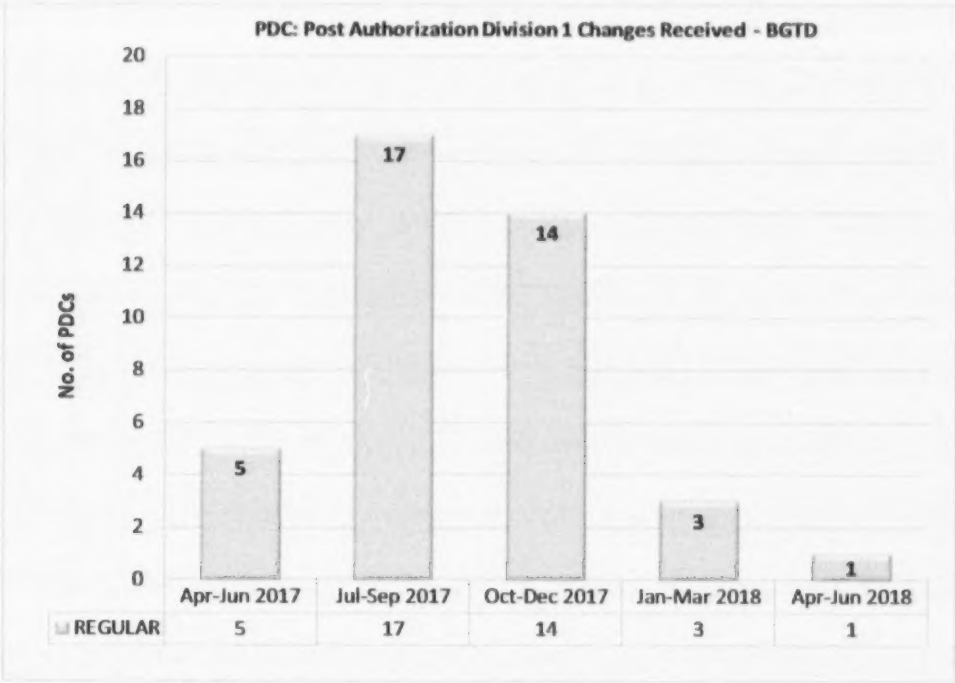


Performance Screening Cycle Completions Showing Percentage Within Target - DINB



Post –Authorization Division 1 Changes - Biologics (PDC-B)

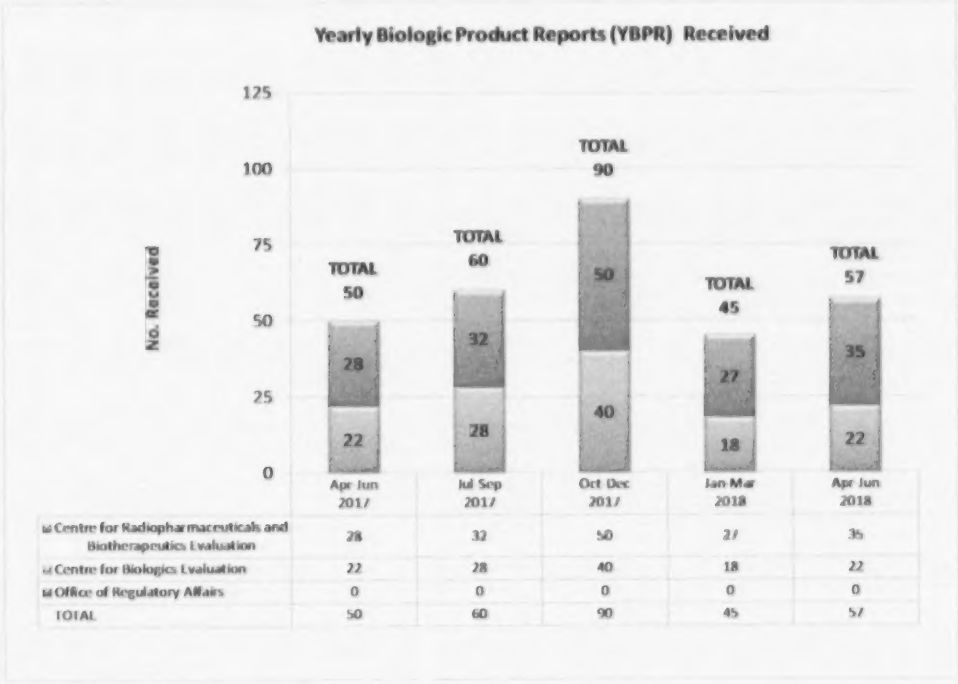
Post –Authorization Division 1 Changes - Biologics (PDC-B) Received



Yearly Biologic Product Reports (YBPR)

[12])

Yearly Biologic Product Report s (YBPR) Received

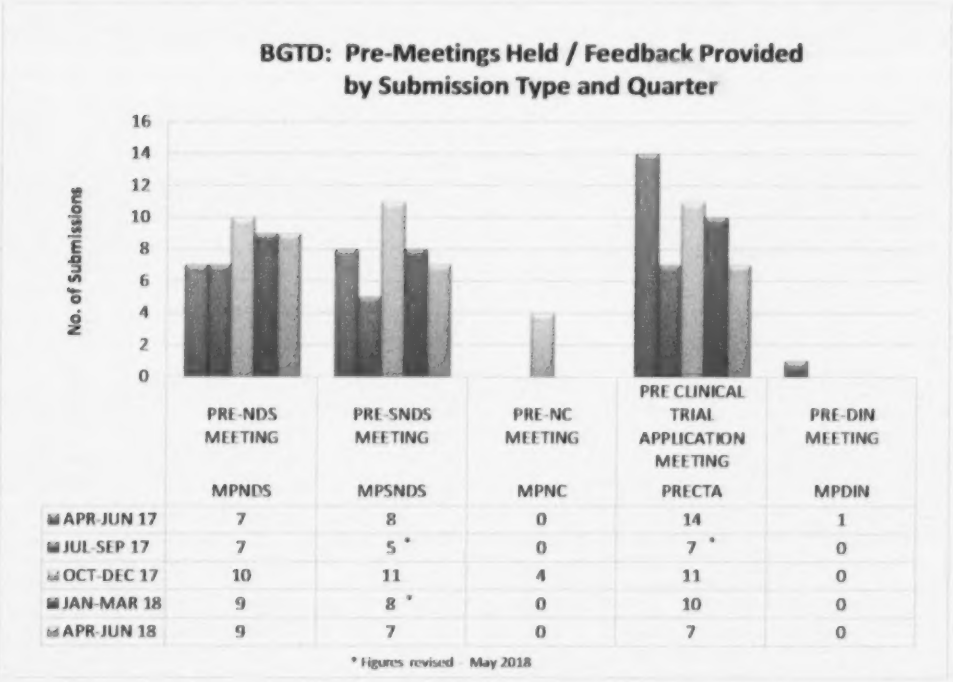


[12] Yearly Biologic Product Report (YBPR) is a report that must be submitted annually by manufacturers of all Schedule D (Biologic) drugs. The report contains production information on both drug substance and drug product lots, including test methods and results, reasons for any recalls and corrective action taken, as well as other pertinent post-market information.

Appendix A: Pre-submission Meetings

[13]

Pre-submission Meetings Held / Feedback Provided



	PRE-NDS MEETING	PRE-SNDS MEETING	PRE-NC MEETING	PRE CLINICAL TRIAL APPLICATION MEETING	PRE-DIN MEETING
	MPNDS	MPSNDS	MPNC	PRECTA	MPDIN
APR-JUN 17	7	8	0	14	1
JUL-SEP 17	7	5 *	0	7 *	0
OCT-DEC 17	10	11	4	11	0
JAN-MAR 18	9	8 *	0	10	0
APR-JUN 18	9	7	0	7	0

* Figures revised - May 2018

[13] Prior to filing a submission, the sponsor may request a pre-submission meeting to discuss the presentation of data in support of the submission: For further information, refer to the Guidance for Industry: Management of Drug Submissions